IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

United States of America,	)	
	)	
Plaintiff, *ex rel.*	)	Case No. 1:10cv01381
	)	
Abdul Wattar,	)	
	)	Judge Gaughan
Relator,	)	
	)	
v.	)	
	)	
North Ohio Heart Center, Inc.	)	Filed Under Seal Pursuant to
Dr. John Schaeffer,	)	31 U.S.C. §3730(b)(2)
Dr. Charles O'Shaughnessy,	)	
Gary Zrimec,	)	
Gary Thome,	)	
North Ohio Heart Lab (NOHL)	)	
North Ohio Medical Imaging (NOMI),	)	
EMH Regional Medical Center,	)	
	)	
Defendants.	)	

FIRST AMENDED COMPLAINT
AND JURY DEMAND

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I. INTRODUCTION

1. Qui Tam Relator Abdul Wattar brings this False Claims Act qui tam action involving false and fraudulent claims submitted by a cardiology and related general practice in northeastern Ohio, including in Elyria, Ohio, operated as North Ohio Heart Center, Inc. Defendants who participated in the preparation and submission of false claims include Defendants Drs. John Schaeffer and Charles O'Shaughnessy ("Physician Defendants"); Gary Zrimec; Gary Thome; EMH Regional Healthcare System; and North Ohio Heart Center's related entities, including Ohio Medical Group (OMG), North Ohio Heart Lab (NOHL) - the "Cath Lab," North Ohio Medical Imaging (NOMI), and North Ohio Research (NOR). Relator also alleges that Defendant EMH Regional Healthcare System conspired with the other Defendants to violate the False Claims Act ("Act") and, thus, is liable under the Act for its acts and those of its co-conspirators.

2. North Ohio Heart Center, Inc., through its physicians and related entity Defendants, including the Physician Defendants, routinely charged the United States Government for unnecessary cardiac procedures, tests, imaging, and other medical services that were not medically necessary and, thus, endangered the lives and well-being of patients. Additionally, Defendants billed the United States for services that were inadequate in quality required by the federal payor systems and engaged in prohibited referrals to entities in which the physicians held an ownership interest.

3. Relator Abdul Wattar ("Relator") brings this action to recover damages and civil penalties on behalf of the United States of America ("United States") arising from false

statements and claims made and presented by Defendants, North Ohio Heart Center, Inc., and their agents, employees, and/or co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, as amended ("the Act"). Relator has direct and independent knowledge of Defendants' practices as a result of his personal experiences as an employee of Defendant North Ohio Heart Center, Inc. from 2004 to 2009, the actions he took to try to prevent Defendants' fraudulent billing, and his personal investigation into Defendants' illegal and medically unethical practices.

4. The Act provides that any person who knowingly submits or causes to be submitted a false or fraudulent claim to the United States for payment or approval is liable for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim submitted or paid, plus three times the amount of the damages sustained by the United States. Liability attaches both when a defendant knowingly seeks payment that is unwarranted from the United States and when material false records or statements are knowingly created or caused to be used to conceal, avoid or decrease an obligation to pay or transmit money to the United States. The Act allows any person having information regarding a false or fraudulent claim against the United States to bring an action for himself ("Relator") and for the United States and to share in any recovery.

5. Relator Abdul Wattar is a cardiologist with over 15 years of professional experience as a physician. He is board-certified in both cardiology and internal medicine and completed several post-graduate cardiology fellowships, including a Cleveland Clinic fellowship in cardiology. Relator worked for Defendants from 2004 until mid-April 2009. During that time,

Relator observed Defendants billing Medicare and other health benefit providers for unnecessary surgeries, inadequate examinations, and services improperly provided by providers unable or unwilling to provide services meeting minimum standards of medical practice.

6. Defendants knowingly presented, or caused to be presented, false claims to the Federal Government for services provided in violation of the Act.

7. Because of Defendants' illegal scheme to defraud Medicare, Medicaid, and other programs, patients not only received unnecessary cardiac procedures, tests, and scans, but the Government also paid claims that it would not have otherwise paid in the absence of Defendants' false claims submissions.

II. JURISDICTION AND VENUE

8. The Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. § 3730.

9. The Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process, and because Defendants transact business and can be found in the Northern District of Ohio.

10. This Court has supplemental jurisdiction over this action, pursuant to 28 U.S.C. § 1367, in that Relator's supplemental state law-based claims form part of the same case or controversy as his federal claims.

11. Venue is proper in the Northern District of Ohio pursuant to 31 U.S.C. § 3732(a) because Defendants can be found and transact business in the Northern District of Ohio.

12. In accordance with 31 U.S.C. § 3730(b)(2), this Amended Complaint and the prior Complaint was filed under seal and will remain under seal for a period of at least 60 days from its filing date, and shall not be served upon the Defendants until after the Court so orders.

13. This lawsuit is not based upon prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation, in a Government Accountability Office or Auditor General's report, hearing, audit, or investigation, from the news media, or in any other location as the term "publicly disclosed" is defined in 31 U.S.C. § 3730(e)(4)(A), *amended by* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010). Relator has, however, affirmatively disclosed the allegations to the United States Government prior to filing suit.

14. To the extent that there has been a public disclosure of information in this Complaint, such information is not that upon which the allegations of this Complaint are based or Relator is an "original source" of this information as defined in 31 U.S.C. § 3730(e)(4)(B), *amended by* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010). Relator possesses direct and independent knowledge of the information in this Complaint, including information he acquired in the course of his employment with Defendants and thereafter. Relator voluntarily provided the Government with his information prior to filing this action and prior to any amendments thereto, pursuant to 31 U.S.C. § 3730(e)(4), *amended by* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010). Relator's information substantially supplements and augments the information previously known to the United States.

15. Relator Abdul Wattar is a resident of Ohio and a citizen of the United States. He is currently employed full-time as a hospital-based cardiologist in southwestern Ohio.

III. PARTIES

A. Relator Dr. Abdul Wattar

16. Dr. Wattar is a Board-certified Cardiologist and Internist. He completed his cardiology residency at the Cleveland Clinic Foundation in 1994. He later completed a Research Fellowship at the Cleveland Clinic in Molecular Cardiology, and Fellowships in Cardiovascular Diseases at Temple University Heath System in Philadelphia and at Illinois Masonic Medical Center in Chicago.

17. Dr. Wattar is a licensed physician in the state of Ohio and has never been the subject of any disciplinary action. He is a member in good standing of the American College of Physicians, the American College of Cardiology, and the Ohio State Medical Association, and he has never had privileges revoked at any medical institution. Dr. Wattar has received several awards recognizing his commitment to patients and his scholarship. Dr. Wattar has published scholarly articles and makes presentations in the field of cardiology.

18. After completing his residency and fellowships in June 2001, Dr. Wattar went into private practice. In 2004, he joined the North Ohio Heart Center, Inc. where he began working in June 2004 as an employee. Dr. Wattar left North Ohio Heart Center, Inc. in April 2009.

19. In his current work as a cardiologist, Dr. Wattar sees patients, provides consultation services, performs procedures, sees out-patients, performs stress testing, reads echocardiograms, performs and reads transesophageal echocardiograms, and responds to

Emergency Room physicians' requests for assistance or other consultations within the hospital where he works. He only sees patients at the hospital.

B. Defendant North Ohio Heart Center, Inc.

20. Defendant North Ohio Heart Center, Inc. is a large cardiology and primary care practice, headquartered in Elyria, Ohio, in Lorain County, west of Cleveland. It has other offices across northeastern Ohio in Lorain, Medina, Sandusky, and Cuyahoga County. The practice was founded 30 years ago. In August 2010, it was announced that North Ohio Heart Center became part of the Defendant EMH Medical Center health care system.

21. Defendant North Ohio Heart Center employs approximately 31 cardiologists. The cardiologists see patients, perform procedures and tests, and consult with other physicians.

22. There are also a number of nurse practitioners and physicians assistants. At the time that Dr. Wattar was most recently at NOHC, nurse practitioners were in the Elyria, Lorain, and Westlake offices.

23. North Ohio Heart Center also employs a number of non-cardiologists, who perform services within a separate unit, called Ohio Medical Group (OMG). North Ohio Heart Center also employs a number of nurse practitioners and physicians assistants. At the time that Dr. Wattar was most recently at NOHC, nurse practitioners were in the Elyria, Lorain, and Westlake offices.

24. North Ohio Heart Center is a very profitable practice. The annual profit/revenue was about $40 million in the years that Dr. Wattar was part of the practice, although revenue fell after August 2006. The physicians' salaries totaled $10 million, thus averaging about $310,000

each, plus approximately more than $180,000 in bonuses and allowances on an annual basis. The physicians enjoyed a generous family benefits package and paid vacation. Additionally, all partners/shareholders in the practice shared in the substantial revenues from the practice and the related diagnostic and other service companies. Personal income of the senior partner physicians from all aspects of the practice regularly exceeded $1 million annually.

25. Defendant North Ohio Heart Center, Inc. has affiliated or related entities, including North Ohio Health Laboratory (NOHL), the Elyria Hospital cath lab; North Ohio Magnetic Imaging (NOMI), the imaging company located at 2211 Crocker Road, Westlake, Ohio; and Diagnostics, the stress test lab facilities located at several locations.

26. The North Ohio Heart Center's related Ohio Medical Group (OMG) has about 24 doctors who are not cardiologists, most of which are internists and family practitioners. The practice also includes or recently has included a nephrologist, an obstetrician/gynecologist, and a hematologist/oncologist.

27. The purpose of OMG was to generate referrals to the far more profitable cardiology practice. OMG was also used to generate referrals to the various parts of NOHC and its affiliated entities that provided tests, imaging, ultrasound scans, etc. OMG provided a multi-million dollar annual profit to the NOHC partners.

C. Defendant Dr. John Schaeffer

28. Defendant Dr. John Schaeffer is the founder and president of North Ohio Heart Center, Inc. He resides in Ohio. Dr. Schaeffer sees patients in NOHC's Elyria and Lorain offices.

29. Defendant Dr. Schaeffer specializes in general cardiology, consultative cardiology, non-invasive diagnostic testing, and nuclear cardiology. Dr. Schaeffer earned his medical degree from Ohio State University. He did his residency and internship at the University of Colorado-Denver, where he also did a fellowship in cardiology. He is board certified in internal medicine and cardiovascular disease.

30. Dr. Schaeffer led partner meetings, led the practice's executive committee, and largely determined who would be hired, become a partner, and receive bonuses or any other compensation. It was under his leadership that the practice developed its extensive angioplasty practice and its related businesses that made the NOHC so profitable for its physician-owners. Very little occurred in the NOHC practice that was not known to Dr. Schaeffer.

D. Defendant Dr. Charles O'Shaughnessy, Lead Interventional Cardiologist

31. Defendant Dr. Charles O'Shaughnessy is a partner/part owner of North Ohio Heart Center, Inc. He resides in Ohio. He was the principal physician at North Ohio Heart Center, Inc. and EMH Regional Medical Center responsible for Elyria's excessively high rates of angioplasties.

32. Dr. O'Shaughnessy received his medical degree from Medical University (College) of Ohio in Toledo. He did his residency in cardiology and internship in internal medicine at Akron City Hospital. Dr. O'Shaughnessy did a cardiology fellowship at University Hospitals of Cleveland and Case Western Reserve University in Cleveland.

33. Dr. O'Shaughnessy is the lead internventional cardiologist at the practice. His specialties are Interventional Cardiology including Balloon Angioplasty, Laser, Directional,

Brachy Therapy, Atherectomy, Stent Placement, Rotoblator, Peripheral Intervention, Renal Stenting and Abdominal Aortic Aneurysm Stenting. Dr. O'Shaughnessy sees patients in NOHC's Elyria office.

34. Dr. O'Shaughnessy works long hours, scheduling angioplasties four days weekly, all day long, in the Elyria Hospital. He accounts for 80% of NOHC angioplasties. His angioplasty surgery area in the Elyria Hospital cath lab on the second floor resembled an assembly line on the four days weekly that he performed angioplasties. Dr. O'Shaughnessy would perform a very high number of such procedures in a single day, going from room to room, with patients sedated and awaiting stents in each room. There were no patient examinations nor any personal interaction with the patients. Staff moved with the doctor as a unit.

35. On Wednesdays, Dr. O'Shaughnessy does not normally perform angioplasties. Instead, he sees as many as 70 patients in the office.

36. Dr. O'Shaughnessy is responsible for millions of dollars in false claims submitted to the United States Government as a result of the unnecessary nuclear stress tests, catheterizations, and angioplasties–claims he submitted recklessly and knowingly.

E. Defendant Gary Zrimec

37. Defendant Gary Zrime was the Chief Executive Officer of North Ohio Heart Center, Inc. He resides in Ohio. He regularly attended NOHC partner meetings. He, as well as the Chief Financial Officer, was known to refer, in the partner meetings and elsewhere, to the NOHC angioplasty practice, as a "cash cow."

F. Defendant Gary Thome

38. Defendant Gary Thome was the Chief Financial Officer of North Ohio Heart Center, Inc. He resides in Ohio. He regularly attended NOHC partner meetings and other meetings. Along with Defendant Zrimec, he was known to refer, in the partner meetings and elsewhere, to the NOHC angioplasty practice, as a "cash cow."

G. Defendant EMH Regional Medical Center

39. Defendant EMH Regional Medical Center is headquartered in Elyria, Ohio and operates the Elyria Memorial Hospital (EMH), where Defendant Dr. O'Shaughnessy performed thousands of unnecessary angioplasties and where other allegations of this complaint occurred.

H. EMH Regional Medical Center: Elyria Hospital

40. Elyria Hospital, as it is commonly known, is officially named the EMH Regional Medical Center. The Hospital is located at:

630 East River Street
Elyria, Ohio 44035
Phone: (440) 329-7500

41. Elyria Hospital is the location where virtually all of Dr. O'Shaughnessy's unnecessary angioplasties were performed and the site of the unnecessary catheterizations. Elyria Hospital knew or should have known of the NOHC fraud scheme, given the abnormally high rates of angioplasties and catheterizations.

42. On August 24, 2010, after Relator's action was filed, EMH Regional Healthcare System and North Ohio Heart Center, Inc. (NOHC) announced that effective September 1, 2010, NOHC and its primary care division, Ohio Medical Group (OMG) would become part of the

EMH Regional Healthcare System. The now 22 cardiologists and 24 primary care physicians of NOHC/OMG will become employees of a new entity, North Ohio Heart, Inc., created by the EMH Regional Healthcare System. The cardiologists will operate under the name "North Ohio Heart," and the primary care physicians operate as "Ohio Medical Group." All existing services and office locations are unchanged.

43. The headquarters of Defendant North Ohio Heart Center Inc. are located at:

125 E. Broad Street, Suite 305
Gates Medical Center
Elyria, OH 44035

Other North Ohio Heart Center's locations are:

Avon (Finance Office)
1220 Moore Road, Suite B
Liberty Business Park
Avon, OH 44011

Bellevue
1400 W. Main Street
Bellevue, OH 44811

Cleveland
2322 E. 22nd Street, Suite 303
St. Vincent Medical Office
Cleveland, OH 44115

Independence
6701 Rockside Road, Suite 100
Independence, OH 44131

Lorain
3600 Kolbe Road, Suite 127
Physician Offices West
Lorain, OH 44053

Medina
3443 Medina Road, Suite 110
Medina, OH 44256

Middleburg Heights
7255 Old Oak Boulevard, C-408
L. Jon Schurmeier Pavilion
Middleburg Heights, OH 44130

Norwalk
272 Benedict Avenue
Snyder/White Heart & Vascular Center
Norwalk, OH 44857

Sandusky
703 Tyler Street
Building 2, Suite 250
Firelands Professional Center
Sandusky, OH 44870

Westlake
960 Clague Road, Suite 2300
Westlake, Ohio 44145 and
29325 Health Campus Drive, Suite 3
Family Medicine Building
Westlake, OH 44145

I. Defendant North Ohio Heart Lab (NOHL)

44. North Ohio Heart Lab (NOHL), the "Cath Lab," is a joint venture between NOHC and EMH Regional Medical Center ("Elyria Hospital"). It was operated under a 49% share of income to the NOHC practice and 51% to the EMH entity. It is located within the hospital site at 630 East River Street in Elyria.

J. North Ohio Medical Imaging (NOMI)

45. Defendant NOHC's practice-owned imaging company, North Ohio Medical Imaging (NOMI), was utilized by Defendant NOHC to generate false and fraudulent claims for

payment.

IV. FEDERAL HEALTH CARE PROGRAMS

A. Medicare

46. Medicare is a federally funded health insurance program primarily benefitting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. Medicare, the nation's largest health insurance program, provides health insurance to people age 65 and over, those who have end-stage kidney failure and certain people with disabilities.

47. Medicare Part A (the Basic Plan of Hospital Insurance) covers the cost of hospital inpatient stays and post-hospital nursing facility care. Medicare Part B (the Voluntary Supplemental Insurance Plan) covers the costs of physician services, certain pharmaceutical products, diagnostic tests and other medical services not covered by Part A.

48. The Center for Medicare and Medicaid Services (CMS) administers Medicare, but much of the daily administration and operation of the Medicare program is managed through contracts with private insurance companies that operate as Fiscal Intermediaries. Fiscal Intermediaries are responsible for accepting claims for reimbursement under Medicare Part A (and some claims under Part B) and making payments for such claim. "Medicare Carriers" are responsible for accepting and paying claims for reimbursement under Medicare Part B.

B. Medicare Payments to Hospitals

49. Medicare pays hospitals different amounts for various services based, in part, on the setting (e.g., inpatient or outpatient) where the services are performed. Hospitals are generally reimbursed for inpatient services on a "per case" basis. Each inpatient hospitalization

is assigned a Diagnosis Related Group ("DRG") based on the nature and severity of the patient's diagnosis and the services performed. Medicare then pays the hospital a pre-determined reimbursement rate based on the DRG. The pre-determined DRG reimbursement rate is paid to the hospital regardless of how long the patient is admitted or the number of services provided.

50. DRGs are assigned to a case through a process called "grouping." A "grouper" is a type of software that reviews various data related to the hospitalization (especially the patient's diagnosis and the procedures performed) to determine the appropriate DRG for the treatment. In most cases, the procedure performed by the hospital is one of the most significant, if not the determinative, data point affecting the DRG grouper's decision. These procedures are classified and reported using the International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9-CM") system. These codes are commonly referred to as "ICD-9 procedure codes."

51. Payments for hospitals in the outpatient setting also bundle items and services so that hospital providers are paid for the procedures performed, including the cost of equipment. Hospitals use APC Codes (Ambulatory Payment Classifications) to bill for costs associated with outpatient services.

C. Medicare Payments to Physicians

52. Physician services provided in conjunction with a procedure performed at a hospital (on either an inpatient or outpatient basis) are billed and reimbursed separately from the hospital's DRG or APC payment. Like hospital reimbursement, Medicare bases physician reimbursement on the assumption that similar types of procedures consume a similar amount of

resources and, thus, deserve similar reimbursement. Accordingly, Medicare reimburses physicians based on standardized procedure codes - HSPCS and CPT codes, as described below.

53. Each procedure code is assigned a weight or value (called a Resource Based Relative Value unit or "RBRVU") as determined by the Resource-Based Relative Value Scale ("RBRVS"). The payment level for any given procedure is then determined by multiplying the RBRVU value for the code times a conversion factor (which takes into account regional and other variable factors).

54. The RBRVS system is based on the Healthcare Common Procedure Coding System (HSPCS). The HSPCS is a standardized coding system designed to ensure that Medicare, Medicaid and other federal healthcare programs pay for services rendered to patients by attending physicians and other healthcare professionals in accordance with payment schedules tied to the level of professional effort required to render specific categories of medical care. To ensure normalization of descriptions of medical care rendered and consistent compensation for similar work, both programs tie levels of reimbursement to standardized codes.

55. Current Procedural Terminology ("CPT") codes are Level I HCPCS codes and are published and updated annually by the American Medical Association ("AMA"). Base CPT codes are five-digit numbers organized in numeric sequences that identify both the general area of medicine to which a procedure relates (such as "Evaluation and Management," "Anesthesiology," "Surgery," "Radiology" or general "Medicine") and the specific medical procedures commonly practiced by physicians and other healthcare professionals working in that field.

56. The instructions that accompany the CPT manual direct providers "not [to] select a CPT code that merely approximates the service provided." Rather, when none of the standard CPT codes provide an accurate description of the services provided or procedure performed, providers are instructed to "report the service using the appropriate unlisted procedure or service code" (i.e., the special CPT codes provided for use when none of the standard CPT codes reasonably and adequately describe the specific procedure or service provided).

57. Codes listed after each subsection in the CPT Manual and ending in -99 are "unlisted" codes. When a provider submits a claim with a "99" code, it must also provide supplemental information describing the procedure performed so that the carrier may determine the appropriate reimbursement. Correct code assignment occurs after this extra documentation for the claim is reviewed by the carrier.

58. Physicians typically submit claims for professional services on Form CMS-1500. This claim form sets forth the diagnostic code describing the patient's presenting condition and the procedure codes. On the claim form, the physician certifies that the services were "medically indicated and necessary to the health of the patient...."

D. Other Rules Governing Payments to Both Hospitals and Physicians

59. In addition to compliance with other national or local coverage criteria, Medicare requires, as a condition of coverage, that services be reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A). Providers must provide economical medical services and then provide such services only where medically necessary. 42 U.S.C. § 1320c(a)(1). Providers must provide evidence that the service is medically necessary and appropriate. 42 U.S.C. § 1320c-5(a)(3).

Providers must ensure that services provided are not substantially in excess of the needs of such patients. 42 U.S.C. § 1320a-7(b)(6)&(8).

60. Federal law also specifically prohibits providers from making "any false statement or representation of a material fact in any application for any…payment under a Federal healthcare program. See 42 U.S.C. § 1320a-7b(a)(3). The requirement that providers be truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program. See, e.g., 42 CFR §§ 1003.105, 1003.102(a)(1)-(2).

61. It is unlawful for a physician to make a referral that will lead to a claim being submitted to Medicare for services or products supplied by an entity (such as a medical device company) with which the physician has a financial relationship. See 42 U.S.C. § 1395nn(a)(1).

E. Kickbacks/Stark Law Violations

62. The federal healthcare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, are of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal healthcare programs from these difficult-to-detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to over-utilization or poor quality of care.

63. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally funded healthcare

program. 42 U.S.C. § 1320a-7b(b). Under this statute, medical device companies may not offer or pay any remuneration, in case or kind, directly or indirectly, to induce physicians or others to order or recommend products or procedures that may be paid for by a federal healthcare program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a company that has, as one of its purposes, inducement of a physician to perform additional procedures using the company's products.

64. Compliance with the Anti-Kickback law is a precondition to participation as a healthcare provider in federal healthcare programs. Either pursuant to provider agreements, claims forms, or other manner, hospitals and physicians who participate in a federal healthcare program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

V. ALLEGATIONS

A. Dr. Wattar's Experience at North Ohio Heart Center, Inc.

65. At North Ohio Heart Center, Dr. Wattar did not have an established practice with patients of his own, nor was he taking over the patient load of any other physician. Instead, upon joining North Ohio Heart Center, he took calls from several local hospitals, including Fairview, St. John West Shore, and Southwest General Hospitals. Dr. Wattar expected that he would spend a number of years developing his own practice with patients of his own.

66. In 2006, Dr. Wattar became concerned when he learned, from a study conducted by the Dartmouth Medical School, that Elyria, Ohio had one of the highest rates of angioplasties in the United States. This study was published in the *New York Times* on August 18, 2006. While

Dr. Wattar's duties did not entail angioplasty procedures and he did not work in the NOHC Elyria office or the Elyria Hospital, he was concerned about the medical decision-making that resulted in such high rates of angioplasty procedures.

67. The President/Chair of the North Ohio Heart Center practice, Dr. John Schaeffer, nonetheless told the NOHC doctors, including in partnership meetings, to maintain their level of angioplasties.

68. Dr. Wattar's practice was based in the NOHC Westlake office until the NOHC management insisted that he begin reading stress tests and performing other services two half-days a week in the Elyria office. At the end of 2007, Dr. Wattar was asked to work in the Elyria office two days a week and in the Westlake office three days a week, beginning in January 2008.

69. Dr. Wattar anticipated, based upon his agreements and discussions with North Ohio Heart Center, Inc., that he would be asked to join the practice as a partner in 2006, but that did not occur.

70. In the following year, 2007, Dr. Wattar was invited to become a partner and was given proposed partnership contractual documents. Dr. Wattar hesitated in becoming a partner due to his concems about the practice group's high rates of angioplasties and the medical basis for such high numbers of stents.

71. While Dr. Wattar did not ever choose to become a partner, he was invited to join the doctors' partnership meetings and began attending those partners' meetings in 2008. As a result, he quickly learned that the primary focus in these meetings was finances, not patient care. Many details of the practice were discussed in depth. This experience led him to be even more

hesitant to join the practice due to ongoing concerns he had about the propriety of the practice's medical decision making and the emphasis placed upon high levels of patient procedures and patient referrals to related diagnostic entities, regardless of medical necessity.

72. Dr. Wattar reported to NOHC CEO, Gary Zrimec, in mid-2008, that it was the practice at North Ohio Heart Center, Inc. of its physicians to order and conduct unindicated stress nuclear tests, and that it was the practice of one or more NOHC physicians to prepare falsified reports about stress test results. In emails, Gary Zrimec denied that there was a problem.

73. In early 2009, Dr. Wattar decided to leave North Ohio Heart Center. The triggering event was when one of his own patients, a woman in her 80's, without any advance notice to the patient or Dr. Wattar, her attending physician, received an unnecessary stent. The procedure was performed without any medical indication of the need for the stent and without patient consent to perform additional coronary and peripheral angiograms. At the time, the patient was to get a carotid angiogram alone on an elective, not emergency basis.

74. In January 2009, Defendant Dr. O'Shaughnessy performed multiple staged stents on Dr. Wattar's patient's coronary arteries and left subclavian artery. Prior to performing the above described additional angiograms, he never physically examined the patient and never observed symptoms or obtained diagnostic evidence indicative of an artery or other blockage needing a stent. He also failed to consult with the physicians who regularly treated the patient prior to performing the procedures on the patient without her consent. Defendant Dr. O'Shaughnessy caused the patient's medical records to be falsified, recording symptoms of non-existent chest pain. Dr. Wattar had been caring for the woman and knew that she had no chest pain.

75. On January 29, 2009, Dr. Wattar emailed Defendant NOHC's president, Defendant Dr. Schaeffer, about Dr. Wattar's patient on whom Defendant Dr. O'Shaughnessy had performed multiple staged stents without medical reason, without consent of her attending physician, and without consent of the patient. Dr. Schaeffer responded by saying he would review the case.

76. In March 2009, Dr. Schaeffer finally convened a 3-member so-called "peer review committee" that included Dr. O'Shaughnessy himself and two other NOHC cardiac interventionalists. Dr. Schaeffer said the committee determined that it was acceptable for Dr. O'Shaughnessy to have performed the surgery and completely exonerated Dr. O'Shaughnessy.

77. The event involving this patient was the culminating event in an escalating pattern of concern that resulted in Dr. Wattar resigning from NOHC.

B. North Ohio Heart Center, Inc.'s "Recycling" of Patients

78. Because they could not increase the Elyria and west Cleveland areas's population, the North Ohio Heart Center instead steadily grew over a 30-year period by increasing the quantity of patients' physician visits and procedures. They did this by "recycling" the same patients over and over again, setting up a system intentionally designed to assure that physicians and other staff conducted needless and medically unnecessary tests, images, scans, stress tests, procedures, heart catheterizations, and angioplasties to insert stents. Adding to the patient recycling revenue stream were revenues from related business entities, to whom the practice required that physicians refer patients for diagnostic imaging, stress tests, and catheterizations.

79. Defendant NOHC's Chief Financial Officer, Gary Thome, regularly attended NOHC partner meetings. He was known to refer, in the partner meetings and elsewhere, to the NOHC angioplasty practice, as a "cash cow." After the 2006 *New York Times* article, Mr. Zrimec advised the physicians to maintain their levels of angioplasties.

80. In 2008, Gary Thome reported to the NOHC partners that the number of angioplasties had declined substantially after the *Times* article and encouraged them to keep up their angioplasty procedure levels.[1]

C. Defendants' Use of the NOHC "Cath Lab" to Generate False Claims

81. Opened in about 2005, the joint venture "Cath Lab" of Defendants NOHC and EMH was located on the hospital's fourth floor. Consisting of beautiful suites, it was purely a diagnostic lab, handling only diagnostic cardiac catheterizations.

82. All NOHC physicians treating patients in the Elyria office and nearby were expected to use the NOHL lab for diagnostic catheterizations, not the Elyria Hospital second floor facility or any other facility elsewhere.

83. After a cath lab test, if the patient's lab tests were interpreted as positive for needing a stent, as it often did in Elyria and with NOHC, the patient would not be moved two floors to the more complete facility on the second floor of Elyria Hospital the same day for the procedure, as is the practice in virtually all other cardiology treatment centers. Instead, the

[1] A number of doctors have left the practice as a result of the *New York Times* article. In addition to those otherwise mentioned in this document, Dr. David Grech left the practice rather abruptly in 2007. A general cardiologist in the NOHC Elyria office, he is currently practicing medicine in Florida.

NOHC patient was brought back in several weeks later for the angioplasty, but this time to the second floor Elyria Hospital cath lab, which also had facilities to perform angioplasties.

84. The NOHL cath lab thus not only generated additional profits to the practice, but it assisted NOHC in staging cardiac procedures, dividing the normal catheterization and angioplasty procedure into two different days, thus billing even more for the same physician service. NOHC's practice of of dividing up the patient cardiac procedures is called "staging."

85. The United States' Health and Human Services Center for Medicare and Medicaid Services (CMS) billing rules do not permit the routine staging of patients. Procedures that are staged are only permitted to be reimbursed if there was a documented medical reason, such as an adverse patient reaction to the dye used in the diagnostic catheterization, kidney failure, etc. Additionally, conducting the catheterization procedure on the same day as an angioplasty or stent, during the same operative session, will normally reduce the amount of the billing.

86. Absent staging for specific, bona fide medical reasons or new and different symptoms, CMS does not permit billing by the provider for separate diagnostics catheterizations and angioplasty procedures.

87. NOHC failed to indicate a reason in each patient's files for the failure to conduct a "same day" procedure. The desire of NOHC physicians to increase the practice's profits and the fact that their lab lacked angioplasty facilities is not a valid medical reason for staging the procedure over two days.

88. Defendants NOHC, Schaefer, and Zrimec "red-lined" NOHC physicians if they failed to send enough patients to NOHL.

D. Defendants' Use of the North Ohio Medical Imaging (NOMI) to Generate False Claims

89. Defendant NOHC set up its practice-owned imaging company, North Ohio Medical Imaging (NOMI) as a profit-generating business. Despite the NOHC doctors referring all their patients to their own imaging company, NOMI was losing money and had a sizable debt arising from acquisition of the imaging equipment.

90. Defendant EMH knew that NOHC's NOMI venture was losing money. But, when federal anti-kickback and self-referral laws became even more restrictive of physician-owned businesses to which physicians self-referred, Defendant EMH helped NOHC by agreeing to buy NOMI in 2009 and pay NOMI's debt.

91. In exchange for the purchase and relief from the debt, the NOHC physicians agreed that they would continue to refer their patients to the NOMI imaging facility, a kickback prohibited by law.

92. Defendants NOHC, Schaefer, and Zrimec "red-lined" NOHC physicians if they failed to send enough patients to NOMI.

E. Medical Information about Cardiac Conditions and Procedures

1. Blocked Coronary Arteries

93. Patients with blocked coronary arteries have a build-up of a fatty substance called plaque inside their heart arteries. This build-up can lead to chest pain or a heart attack. Patients have several options to address this problem including drugs, bypass surgery and angioplasty. Angioplasty is considered an aggressive intervention that can be performed at a hospital by a

cardiologist. Angioplasty is where a balloon catheter is inserted into the arteries and blown-up in order to compress the plaque and widen the arteries. Typically, a stent is then placed in the treated portion of the artery in order to reduce the possibility of the artery becoming blocked or narrowed again. Bypass surgery is riskier and more expensive, but requires a patient to be referred to a surgeon. There were and are no surgeons and no cardiac surgeons associated with NOHC.

94. Beginning in 1993, stents were made of a metal mesh, roughly made like an umbrella. A stent is is inserted through the body and up to the heart to the narrowed portion of the artery that is substantially blocked (more than 50%). The stent thus artificially opens up the narrowed artery and allows more normal blood flow.

95. Because stents have a tendency to cause the body to grow cells to defend themselves against the foreign item now inside the body and thus cause re-stenosis, drug-eluting stents have become more common. A drug-eluting stent is a stent that is enveloped in a special drug, such as a cancer treatment drug that blocks cell growth. Such drugs include anti-neoplastics like sirolimus (also known as rapyamycin or the trade name Rapamune) or anti-proliferatives, like TAXOL (paclitaxel). The drug-eluting stent is intend to impede cell growth or so called intimal hyperplasia and the re-stenosis process.

96. The more stents a patient recieves, the more likely a patient is to have stenosis, which is an abnormal narrowing of the arteries. Stenosis not only endangers a patient's life and health, it may lead to open heart surgery. Open heart surgery has a 4% to 9% mortality rate.

97. Stents are placed only after various diagnostic tests are conducted that advise the interventionalist cardiologist where in the artery the blockage exists and, thus, where the stent should be placed in order to open the artery.

98. The human heart has three main arteries, the right, left, and "up front." The nuclear pictures from the pre-stent procedure identify and prove the decreased blood flow arising from the blockage. The nuclear tracer materials, injected through the patient's vein, are pumped into the heart by the body and distributed throughout the heart and its arteries. The nuclear tracer then creates a pattern in the heart that is made visible by means of the Gamma radiation camera used in the nuclear stress lab. If there is a blockage, the camera's image would show which artery is blocked. Absent such evidence, no stent procedure should go forward without other convincing associated clinical factors.

99. When inserting a cardiac stent without proper clinical evaluation and without test results suggestive of ischemia, there is no medical basis for the procedure.

2. The Dartmouth Medical School Study Finds Elyria Has High Rate of Angioplasty Procedures

100. In mid-2006, an epidemiological study by the Dartmouth University Medical School, highlighted that Lorain County had one of the highest rates for surgical stent interventions (angioplasty) in the nation. The study, published in the Dartmouth Atlas of Healthcare Studies of Surgical Variation, analyzed the number of heart catheterizations performed in Elyria, Ohio, where North Ohio Heart is the dominant cardiology group, and studied the rates of percutaneous coronary interventions (angioplasty or stent procedures done via

a needle-puncture in the skin rather than by using a scalpel to expose organs) among Medicare enrollees in 2000.

101. Elyria, Ohio was among the hospitals' referral regions where rates of percutaneous coronary interventions were the highes. The 1999 edition of the Atlas pointed out that Elyria's rate of percutaneous coronary interventions was the highest in the United States during the years 1995 and 1996. The rate of percutaneous coronary interventions performed on Medicare enrollees in Elyria Hospital rose steadily between 1992 and 2003 from 5 procedures per 1000 enrollees in 1992 to 9 procedures in 1998 and reaching 13.5 procedures per 1000 by 2003. The rates of percutaneous coronary interventions in Elyria were about 80% higher than the state average in 1992 and rose much more sharply between 1993 and 1998 from 9.1 to 23.8 procedures per 1000 Medicare enrollees or more than 2.5 times the Ohio average. By 1996, Elyria ranked first and remained the highest rate or second highest rate in the country through 2003 for percutaneous coronary interventions.

3. Issues of Cost, Reliability, and Risk to Patients: Treadmill Tests, Nuclear Stress Tests, Catheterizations, and Angioplasties

102. Treadmill cardiac testing is relatively inexpensive and involves the lowest risk to the patient. As with any testing of the heart, it carries with it some risk of myocardial infarction (heart attack), arrhythmia, and death, although such risks are very, very small. It is often a preliminary test that can be performed to avoid the expense and additional risk of further unnecessary diagnostic procedures. A treadmill test usually involves only several hundred dollars in expense.

103. Nuclear stress tests (myocardial perfusion) involve additional risks that the treadmill alone does not. A myocardial perfusion scan is a nuclear medicine procedure that illustrates the function of the heart muscle (myocardium). It can evaluate many heart conditions from coronary artery disease (CAD) to hypertropic cardiomyopathy and myocardial wall motion abnormalities. However, at the NOHC in Elyria, the primary use of the stress test was simply to generate billings and additional patients for angioplasties. The imaging can often be completed in less than 10 minutes. Abnormalities and small areas of infarction can be identified, as well as the occluded blood vessels and the mass of infarcted and viable myocardium. Of most concern is that the patient is exposed to large amounts of radiation to conduct the test. Thus, with each additional test and dose of radiation, as would occur with annual or more frequent testing or in combination with other unrelated medical procedures involving radiation, the patient's risk is increased substantially. There are also small risks of myocardial infarction (heart attack), arrhythmia, and death. Together, the complication rate is less than 1% (excluding the radiation risks).

104. After the stress test, a cardiologist trained in reading the stress test images studies the images produced--the radioactive material identifying potential areas causing ischemia and representing arterial blockages. The average accuracy rate of qualified readers is about 88%. Shadows or obstructions, most frequently caused by excessive weight or patient obesity, extracardiac overshadowing, motion, etc., cause "artifacts" that impede a completely satisfactory reading.

105. Diagnostic catheterization has similar risks associated with radiation exposure and myocardial infarction (heart attack), arrhythmia, and death. However, it has additional risks that a nuclear stress test does not. There can be infection at the site on the groin where dye is inserted and risk of bleeding that cannot be easily controlled. While excessive bleeding is not a risk for most healthy patients, cardiac patients frequently are taking Coumadin, Plavix, or other blood thinners that make blood clotting much more difficult and may require additional medical care or procedures if bleeding is not controlled. Some patients will develop asthma or bronchspasms arising from allergies to the dye. As with any hospital procedure, there is some risk of a hospital-acquired illness or infection. The cost of a diagnostic catheterization may total several thousand dollars, including hospital charges and physician fees.

106. An angioplasty is significantly more risky to the patient and more costly to the patient, Medicare, or other payors. In addition to all the risks involved with cardiac catheterization, stents can cause restenosis (more blockage), chest pain, chronic angina, heart attack, stroke, kidney failure, rupture of an artery or pericardial perfusion (leakage) requiring further interventions such as open heart surgery, bleeding problems requiring additional medications, and death. These are all unacceptable risks for a patient who does not have a medically indicated need for a stent, confirmed by clinical findings and a valid and reliable stress test or cath lab report.

107. Multiple stents are known to lead to a greater likelihood of a patient requiring open heart surgery in the future. Open heart surgery has a 4% to 9% mortality rate in those

hospitals where the procedure is performed.

108. NOHC has claimed that its high rates of procedures are simply high quality patient care, a type of preventative cardiology. This is simply not the case. Overutilization of tests and procedures is not acceptable medical practice as determined by CMS, the AHA (American Hospital Association) or ACC (American College of Cardiology). An order for a battery of tests, whether a stress test or cath lab procedure, must first be supported by a medical indication or new symptoms and signs (chest pain, shortness of breath, etc.). Absent some indication, knowingly ordering such tests on a routine basis is fraud.

109. Medicare currently pays $10,000 to $15,000 per angioplasty procedure, known as a percutaneous intervention.

F. The Recycled Patient Fraud: "Chickens Come Home to Roost"

110. North Ohio Heart Center grew rapidly during the period from 1995 until August 2006. Defendant Dr. O'Shaughnessy joined the practice as the lead interventionalist in the 1980's. Dr. Kenneth Bescak joined at about the same time. Dr. Bescak was a general cardiologist. He was not formally trained as an interventionalist, but still did such procedures from time to time. He has been semi-retired in Arizona since 2008. Dr. Wattar took on many of his former patients when Dr. Wattar was assigned to Elyria in 2008. Dr. Bescak left NOHC after the 2006 revelations of the NOHC's unusually high angioplasty rates.

111. During his employment, Dr. Wattar became more aware that North Ohio Heart Center created its own growth through a practice that he has come to call "recycling patients." Defendant Dr. Schaeffer and others in leadership, including Defendant Gary Zrimec, often

remarked, in conjunction with discussions of increasing procedures and, thus, revenues, that the "chickens come home to roost." The "chickens come home to roost" phrase was used to mean that the practice profited when patients came back, time and again, for more procedures performed by NOHC. Through this scheme, the practice, which is situated in a region that is losing population, was able to grow without substantially increasing the actual number of patients that were treated by the practice.

112. The Elyria area simply was not large enough to generate the revenues that the North Ohio Heart Center leadership wanted to generate, particularly with the world-reknowned cardiologists at the Cleveland Clinic, who are top rated nationally and internationally for cardiac research and interventions, and who are competing for patient business.

113. Because the number of cardiac patients and procedures would not legitimately generate desired revenues, the NOHC practice developed a method to "recycle" patients. Having exhausted their potential patient base in the area, the practice went back to their existing patients, over and over again, to generate revenues, without medical justification for many of the services performed and billed to patients and third-party payors, including Medicare and Medicaid.

114. Defendant Dr. Schaeffer repeatedly told NOHC physicians and staff that if Cleveland Clinic second-guessed the treatment provided by NOHC physicians, that this was just jealous comments by a competitor who could not be trusted. In fact, however, it was Cleveland Clinic physicians who performed the much more complex and sophisticated heart bypass operations at Elyria Hospital, rather than the interventional cardiologists from NOHC who were responsible for the excessive stenting procedures.

G. The Mechanism for the Excessive Angioplasties: Stress Nuclear Testing

1. Stress Nuclear Testing - Standard Medical Practice

115. A nuclear stress test measures blood flow to your heart muscle both at rest and during stress on the heart. The purpose of the nuclear stress test is to serve as a sort of "gate keeper" to identify those patients who are appropriate subjects for cardiac catheterization.

116. A nuclear stress test is used to gather information about how well the heart works during physical activity and at rest. A nuclear stress test is performed similar to a routine exercise stress test, but provides images that can show areas of low blood flow through the heart and areas of damaged or ischemic (meaning starved of oxygen) heart muscle. A nuclear stress test usually involves taking two sets of images of the heart. One set is taken during an exercise stress test while exercising on a treadmill or stationary bike, or with medication that stresses the heart, and another while the patient is at rest. There is also a chemical stress test used for those few patients unable to engage in the exercise.

117. Nuclear stress tests are given if a patient's doctor suspects coronary artery disease or another heart problem arising from patient symptoms and complaints, or if an exercise stress test alone is not enough to pinpoint the cause of symptoms like chest pain or shortness of breath. A nuclear stress test may also be recommended in order to guide treatment if the patient has already been diagnosed with a heart condition that requires medical intervention.

118. A nuclear stress test is not routinely done without a medical indication, such as a patient complaining of shortness of breath and chest pain suggestive of a heart condition. Normally, physicians would rely upon reports of new symptoms prior to ordering a test and

would not do so simply because an asymptomatic patient had a stent in the past.

119. When the testing is done with little medical indication for the test and no symptoms to guide the reading, the nuclear test cardiologist reader loses sensitivity and the ability to focus on the patient's blockage and the severity of the blockage. The general accuracy rate, nationwide, for nuclear stress tests is 88%. That is, about 12% of the test results are falsely positive or negative for abnormality. Some of the reasons for false readings are "artifacts" in the image, frequently caused by the patient moving, excessive weight or obesity, and the like. Thus, the absence or presence of symptoms of chest pain or shortness of breath are important to determine whether any abnormality is likely.

2. Stress Nuclear Testing - NOHC Style

120. North Ohio Heart Center's primary interventionalist, Dr. O'Shaughnessy, developed a system of requiring nuclear stress tests annually for all Elyria patients with stents. Specifically, it was North Ohio Heart Center's practice, as carried out under the direction of Dr. Charles O'Shaughnessy, to contact his thousands of stent patients at one-year intervals and advise them it was time to come in for their nuclear stress test. Patients with no symptoms and with prior history of intervention were ordered annual nuclear stress testing repeatedly and unnecessarily. There was no medical or clinical necessity for the tests, making the tests not compensable under Medicare and Medicaid.

121. Upon arrival at the NOHC office for a nuclear stress test, a "blue sheet" was filled out by North Ohio Heart Center personnel. The form would state that the patient was having symptoms such as shortness of breath or chest pain, when, in fact, neither the patient's own

statements nor the patient's medical chart corroborated said symptoms. These symptoms were intentionally and fraudulently coded as part of North Ohio Heart Center's billings to Medicare. Based upon the fraudulently-induced patient symptoms resulting in medically unwarranted nuclear stress testing being performed, many patients were thereafter referred for interventional heart catheterizations predicated upon the false patient symptoms listed in the blue sheet.

122. Stress nuclear testing that is not medically indicated is not just a matter of unnecessary costs and time spent by the patient. Such nuclear testing causes needless radiation exposure and could expose the patient to complications and further potentially harmful, unnecessary procedures.

123. North Ohio Heart Center billed Medicare and Medicaid, and was subsequently paid by the Government, for intensive cardiac testing that was medically unnecessary. An individual stress test cost the Government $400 to $800, depending on the year in which it was performed. Over the last 15 years, North Ohio Heart Center may have billed the Government for more than $20 million for nuclear stress tests, many of which were unnecessary.

3. Cardiac Catheterization

124. Cardiac Catheterization is a diagnostic procedure where a plastic tube is inserted in the groin with dye and the dye shows up in the heart, with an x-ray-like image showing whether the dye reveals any blockage. Like the nuclear stress test, it also requires a trained physician to read the test results.

125. Defendants North Ohio Heart Center and EMH (Elyria Memorial Hospital) Regional Medical Center had a joint venture for a catheterization laboratory at EMH Regional

Medical Center in Elyria. EMH Regional Medical Center owned 51% of the laboratory and North Ohio Heart Center owned 49%. The joint venture was created under the premise that North Ohio Heart Center would create business for the catheterization laboratory through referrals. The substantial majority of the heart catheterizations that NOHC's Elyria physicians performed were at this NOHL laboratory.

126. The unnecessary heart catheterizations performed by North Ohio Heart Center resulted in significant billings being presented to the Government through Medicare.

H. The NOHC Stress Nuclear Testing Recycling Cycle

127. When he began reviewing stress nuclear test results several days each week in the Elyria office in January 2008, Dr. Wattar had access to full patient files, including records copied from the patients' Elyria Hospital patient files. He began to notice high rates of stents, a practice of nurse practitioners entering an order for a stress test a year in advance of each patient's annual appointment, and other mechanisms and evidence of actions taken to increase patient procedures. In particular, he eventually detected a pattern of actions by Dr. O'Shaughnessy and the practice that were intentionally designed to result in high rates of medically unreasonable and unnecessary tests and angioplasties.

128. In April or May 2008, Dr. Wattar discovered charts in the practice's Elyria office that showed a large number of patients had received stents without appropriate medical indication and documentation.

129. Dr. Wattar personally reviewed over 70 patient charts dating back to the 1990s through 2008. In that review, Dr. Wattar noted that many patients had received stents, including

one who had received as many as 20 stents over the years and another who had undergone 3 cath lab procedures at South West General Hospital by Dr. Qarab Syed and Dr. Donald Cho (NOHC partners), spaced 4 months apart and described no significant obstruction on each testing. Most of the irregularities appeared in the files of Dr. O'Shaughnessy's patients.[2]

130. NOHC does not observe basic medical standards of care in ordering nuclear stress tests, diagnostic catheterizations, and angioplasties. The goal is to self-refer patients for more and continued patient testing and procedures.

131. Below is the cycle that Dr. Wattar came to learn, during the 15 months he spent reading stress nuclear tests and attending patients in the Elyria office. The following is a summary of the procedure he learned, through experience, review, and observation at the Elyria office where most of the interventions were done, that was practiced to result in abnormally high rates of stress testing, cath lab procedures, and angioplasties:

a. Nurse practitioners working with Dr. O'Shaughnessy annually see practice patients who have had a stent. At that visit, the patients are told that they will be scheduled for a stress test in a year. However, nothing in the patient's chart would justify such an order, as the patient denied chest pain and shortness of breath and the practitioner's review of systems was normal.

b. Dr. O'Shaughnessy had two nurse practitioners who were involved with this, Brenda Life and Susan Robinson. Every time they would see a patient they would say, "do the stress nuke test one year from now." Susan Robinson left the practice and was said to be unhappy with them. She was vocal about their practice in terms of not approving of this. She felt she was forced to do things she was not happy to do.

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[2] A list of those patient numbers as used by the practice was previously provided to the Department of Justice by Dr. Wattar in July 2009.

c. The NOHC practice apparently had some sort of tickler system that caused a medical assistant to contact Dr. O'Shaughnessy's patients annually and advise that it was time to schedule a stress test. Most patients complied.

d. Upon the patient's arrival for a stress test appointment, medical assistants, nurses, or nuclear stress test technicians filled out a blue-colored sheet indicating the patient's vitals (heart rate, blood pressure, etc.). No physical examination was performed. The technician or other staff injected the nuclear medicine and observed the electrocardiogram undertaken during the procedure. Vitals are taken by the Registered Nurse and Nuclear Technician present. The blue sheet would also indicate, routinely, that the patient had shortness of breath and chest pain, regardless of whether the patient had complained of any symptoms. The blue sheet would also have the initials of the physician who was somewhere on the premises, as that was required to bill the stress test, but this physician had nothing to do with the services or the report.

e. The patient's nuclear stress test was conducted by the technician, with a nurse present, and then the patient left. No physician or nurse practitioner interacted with the patient, took a medical history, or conducted a physical examination.

f. The stress test normally was read by Dr. Michael Vacante, DO, FACC, who routinely found ischemia (blockage) and would describe in a written report where he thought the blockage existed. Dr. Vacante read approximately 85% of Dr. O'Shaughnessy's patients' stress tests and the majority of the stress tests at Elyria. Dr. Vacante would describe his impressions as to where the likely ischemia was (the likely blockage). Dr. Vacante had a much higher rate of reading stress nuclear studies as requiring catheterization or stents than Dr. Wattar and other physicians who read stress tests at NOHC and a much higher rate than was Dr. Wattar's experience at various offices in the Cleveland area. There was little or no peer review of Dr. Vacante. As infrequently as once or twice a year, one of his readings was checked and, even then it was done by someone who was not currently a frequent stress test reader.

g. When Dr. Wattar, an experienced, trained, qualified, and frequent stress test reader, read the same images that Dr. Vacante had found to be positive, Dr. Wattar concluded that many were not positive. From time to time, Dr. O'Shaughnessy would ask Dr. Wattar to re-read an image that Dr. Vacante had already read and found positive. Dr. Wattar found that these were negative for ischemia. Dr. Vacante's rate was 3 to 4 times that of other readers in the practice, in the area, and in the State of Ohio. While some physicians tend to over-read films as falsely negative and others tend to over-read as falsely positive, few have

such highly erroneous positive readings as Dr. Vacante. Generally only those stress test images that were free of shadows or other vague suggestions of blockage passed through Dr. Vacante's hands and were read as not meriting a catheterization.

h. Dr. O'Shaughnessy does not read stress nuclear tests and does not know how to read them. He relied upon the impressions of his partner, Dr. Vacante, in determining whether any further testing or stent procedures were required. Occasionally, in situations where there was no medical basis for differing treatment, Dr. O'Shaughnessy would ask Dr. Wattar or another physician who did not normally read stress test results for Dr. O'Shaughnessy for a second opinion on certain patients. This would occur when Dr. Vacante's impression was that there was a blockage of more than 50%. In Dr. Wattar's experience in performing these second opinions, he rarely or never found a blockage in these stress test results, even thought Dr. Vacante had claimed an operable blockage.

i. Upon review of Dr. Vacante's report, Dr. O'Shaughnessy would direct NOHC office staff to call the patient. They told the patient that Dr. O'Shaughnessy needed the patient to come in for a catheterization because the stress test showed a blockage and that catheterization was required.

j. For Dr. O'Shaughnessy's patients and for most other patients, any initial diagnostic catheterization was "preferred" to take place at the Elyria Hospital-NOHL lab, rather than the full-service cath facility on the Elyria Hospital second floor. In the fourth floor of the Elyria Hospital, where the practice and the hospital jointly operated the NOHL catheterization lab, with 51% of the revenues flowing to the hospital and 49% to the practice, a very high percentage of cath lab images were read as "positive" for a blockage, regardless of what the images actually showed. While any one of the NOHC cardiologists performed the catheterization, Dr. O'Shaughnessy interpreted the images and caused his own report to issue, leading to his frequent determinations that arteries were blocked by more than 50% and required a stent.

k. Dr. O'Shaughnessy's pre-surgical catheterization report frequently simply says indication: ACVS, meaning abnormal cardiovascular study. The report should indicate which artery requires a stent due to blockage, as nuclear tracer material lights up on the x-ray if there is a blockage on the picture and shows which artery. Dr. O'Shaughnessy's report will indicate a location for the ischemia, but this entry and the ACVS indication in many cases is without basis. This entry is regardless of whether a stent is actually medically indicated by the test results and regardless of where Dr. O'Shaughnessy eventually places the ultimate stent. This code is

essential for billing the subsequent angioplasty. Both the pre-test and presurgical clinical evaluations have to match in order to bill ACVS and get Medicare reimbursement. Medicare pays a hospital approximately $11,000 for an angioplasty involving a drug-eluting stent. A cardiologist is paid approximately $800 for performing the procedure.

l. After diagnostic catheterization, Dr. O'Shaughnessy's patients were frequently contacted by office staff or a nurse a few days later and told that the exploratory diagnostic cath lab results showed that the patient needed a stent, due to a serious blockage of one or more of the heart's 3 arteries. The patient was told that an angioplasty needed to be scheduled in the next several weeks to open up the blockage with a stent.

m. Dr. O'Shaughnessy's patients were routinely and by design, staged for a cath lab procedure that was followed up several weeks later by Dr. O'Shaughnessy performing an angioplasty. The staging of the procedures was the preferred practice, rather than conducting the two procedures simultaneously. Normal medical procedure and the procedure considered appropriate under federal and other billing procedures is for the procedures to be done at the same time. The NOHL Elyria Hospital catheter lab was located on the fourth floor. The hospital's more fully-equipped angioplasty facility was on the second floor. The initial catheterization of the NOHC two-stage process could also occur in the second floor facility, but that was not preferable. In that manner, NOHC and Elyria Hospital could more easily stage the patient for two different billable procedures to increase revenues for the physicians and the hospital.

n. Despite the fact that there was no proven decreased blood flow anywhere that was sufficient (over 50% blockage) to merit a stent and without pre-procedure proper clinical evaluation, Dr. O'Shaughnessy's patients were routinely admitted to the Elyria Hospital for angioplasty procedures. In the procedure, the cardiologist would deploy the drug-eluting stent, a sort of metal mesh umbrella, to open up the blockage. Prior to 1993, when the use of stents began and soon predominated, "balloons" were used to open up blocked arteries.

o. Thus, Dr. O'Shaughnessy's repeat angioplasty patients ended up sedated and undergoing an angioplasty without ever seeing Dr. O'Shaughnessy or any other doctor and without having a provider conduct a physical examination or obtain an accurate patient history demonstrating symptoms of shortness of breath or chest pain, critical clinical indicators prior to conducting any angioplasty. With no accurate nuclear stress test reports and with often-falsified catheterization lab results reports, his patients were wheeled into the Elyria Hospital facility and stenting procedure commenced by Dr. O'Shaughnessy.

p. Frequently, with the patient hooked up to cath lab equipment that measured blockages electronically in each of the three heart arteries (left/right/front), there was no reasonable way for Dr. O'Shaughnessy to claim, in front of hospital staff, technicians, and nurses assisting in the angioplasty procedure, that there was a blockage requiring an arterial cardiac stent. It was plain to the eye and confirmed by electronic data that there was no operable blockage. The stent was thus not inserted where all the prior reports had indicated it should go in the allegedly seriously blocked artery.

q. Faced with a patient who required no intervention based on the actual clinical findings, symptoms, and history, plus armed with erroneous or faked stress test results and a false cath lab report that managed to get the patient into the hospital procedure room, Dr. O'Shaughnessy would put one or more stents in some other place in the patient since there was no blocked artery to match the area of "ischemia" or decreased flow identified in the stress nuclear report or cardiac catheterization x-ray report. Dr. O'Shaughnessy was now performing the stent without any medical basis to do so.

r. To do a stent, you must have at least a 50% blockage as measured in the cath lab room. It is not possible, in front of experienced nursing and other staff, to put the stent in where the artery is clear and there is no blockage. Without real symptoms and no accurate diagnostic report, you have little guidance to find any other blockage. So Dr. O'Shaughnessy would quickly "eyeball" some other part of the heart vessesl that branched off of one of the heart's 3 main arteries. These were all "blockages" that were not large enough to show up on the stress nuclear results. He simply decided, on the spot, where the stent should go. He was doing so without measurement, without stress test, without symptoms, and without advising the patient, the patient's attending physician, or the patient's family. He had the patient in the hospital procedure room, lying on the table, and was determined to insert a stent. Otherwise, neither he nor the hospital could justify the procedure nor would payors reimburse at the high rates desired. The physician's angioplasty fee was about $800, whereas the catheterization fee alone was about $380. Likewise, catheterization results in a hospital charge of about $2000, whereas an angioplasty would result in several times that amount.

s. Afterwards, to justify the medically unnecessary and medically unreasonable stent procedures, Dr. O'Shaughnessy noted in patient records that there were indications of chest pain and shortness of breath and that ischemia was found in different areas than initially identified prior to performing the procedures. These false reports were generated by computer templates and contained information entered by nurses and technicians. Dr. O'Shaughness merely signed the reports and inserted details about where he put the stents, including computer-assisted

drawings. As observed by Dr. Wattar, comparisons of patient records where the patients' stress test results said stents should go and where Dr. O'Shaughnessy actually put the stents showed that most of the time stents were not put where the stress test impression reports said stents were medically indicated.

132. NOHC does not observe basic medical standards of care in ordering the above procedures. The goal is to self-refer patients for more and continued patient testing and procedures.

133. Defendants did not exercise or did not require to be exercised the basic, medically-indicated standards of care prior to NOHC physicians, in particularly Dr. O'Shaughnessy, performing stent procedures on most patients at Elyria Hospital and in performing and interpreting diagnostic testing prior to the stent surgeries.

134. Defendant Dr. O'Shaugnessy was the primary physician who conducted the unnecessary stenting. The other interventionalists in the NOHC practice are Drs. Sheldon, Blankenship, and Naim Farhat. Together they perform about 20% of the NOHC angioplasties at the Elyria Hospital location. Dr. Farhat is considered the "number 3" physician in the practice and serves as the corporate secretary.[3] Dr. Farhat covered the Elyria Hospital cath lab on Wednesdays or other times when Dr. O'Shaughnessy was not there. Occasionally Drs. Blankenship and Sheldon also filled in when Dr. O'Shaughnessy was not in the hospital. Dr. Farhat also saw patients at other hospitals, whereas Dr. O'Shaughnessy normally did not. Dr. Farhat engaged in similarly unnecessary catheterizations and stenting procedures, although these occurred at more than Elyria Hospital, but also at other area hospitals where he worked.

[3] NOHC maintains very lengthy and detailed partnership and executive committee meeting minutes.

135. Defendants should have engaged in pre-surgery assessments and clinical pre-test evaluations and, in some instances, treadmill or non-nuclear stress testing, to determine the likelihood of disease present before performing any nuclear stress testing, cardiac catheterization, and angioplasties. There is a well-established medical standard of care that requires that the above processes be observed and such processes are required to be observed in order for payment for such services by federal and state government payors.

136. With Defendant NOHC's angioplasties performed by Defendant Dr. O'Shaugnessy, there was no assessment or pre-clinical evaluation done. The tests were instead ordered routinely and on the phone without pre-test evaluation.

137. Generally, if there are symptoms or other indications of a heart problem, that will help guide the physician trained to read stress test results or cath lab reports to spot the abnormality indicated by symptoms and other clinical or history findings. Without such guidance, the physician is looking for something that may not exist and for which there is no basis to even look. This leads to false positives and, in the case of NOHC, with its huge financial interest in finding abnormalities, readings that were frequently and intentionally wrong. Indeed, often the only indication of a possible blockage was not supported by symptoms or clinical findings, but was only historical, i.e., that NOHC physicians had previously inserted a stent in the patient.

I. Referring Patients for Stents and Not Open Heart Surgery

138. Because NOHC physicians did not perform open heart surgeries, they had a tendency to order stents when open heart or "bypass" surgery would have been more appropriate.

To accomplish this, patients would undergo an angioplasty for 1 or 2 blockages and then be brought back again when 1 or 2 more "new" blockages are "discovered."

J. Unnecessary Defibrillators

139. Defibrillators are used therapeutically to regulate dangerous cardiac heart rhythms. A newer medically accepted guideline is to use this device to assist patients with weak hearts as measured by patients' "Erection Fraction." "Ejection Fraction" is the strength of the heart muscle. If the "Ejection Fraction" number is lower than 35%, there is a medical indication for the defibrillator device to be inserted. When used therapeutically, the device is inserted into the body and two wires are placed inside the heart to give shocks to patients with abnormal heart rhythms. Usually defibrillations are done after a study, going through the groin, where the cardiologist looks for sources of the rhythm problems and produces the episodes in patients.

140. Rather than observe reasonable and necessary medical practices for debrillator device usage in patients, Dr. O'Shaughnessy would inject a little dye intentionally during the regular cardiac catheterization and then, because only a small amount of dye was visible, claim that the heart function was low. Had he injected a normal amount of dye, there would have been a valid test and, most likely, the dye would have shown a normal flow. By using the small amount of dye, he used the resulting evidence of low heart function to justify sending numerous patients off to have a defibrillator inserted, rather than through the normal process utilized by cardiologists for identifying patients whose medical condition required a defibrillator. The normal process, again after patients complained of symptoms suggestive of a need for a

defibrillator, was for a cardiologist to evaluate whether the patients suffered from low heart function through a different test called a Muga scan.

141. Dr. Stephen L. Moore, D.O., formerly a physician at NOHC, inserted defibrillator devices, at times in violation of general medical indications for their use, as a result of Dr. O'Shaughnessy's spontaneous diagnosis of a "weak heart" during routine cardiac catheterization and without other medical indications suggestive of the need for a defibrillator.

142. Dr. Moore had a very high rate of inserting defibrillators, much higher than would be expected for a physician practicing in the area where we worked.

143. Certain NOHC personnel also had a practice of using a modifier to add costs for every single patient who underwent defibrillation. Medicare permits the use of the modifier in those limited instances where a change in the battery of the defibrillator requires a change in the size of the pocket. Thus, NOHC's method was to code all patients as having the pocket revision, regardless of whether they had it or not.

VI. KICKBACKS/STARK LAW VIOLATIONS

A. North Ohio Heart Laboratory - NOHL's Cath Lab at Elyria Hospital

144. There was constant pressure by the NOHC leadership for the staff cardiologists to make referrals of patients to the catheterization laboratory, as the billings for the laboratory resulted in substantial payments being made to North Ohio Heart Center partners. North Ohio Heart Center's president, Dr. John Schaeffer, and CEO, Gary Zrimec, gathered information on each cardiologist's number of referrals to the joint catheterization laboratory and presented the information to the cardiologists in their NOHC partner meetings, openly applying pressure to the

physicians to solicit further referrals, as if it was a competition among the doctors to see who could generate the most referrals to the catheterization lab.

145. NOHC physicians' payment structure included productivity bonuses that were based on the numbers of referrals made, not on the number of procedures the physicians actually performed. Cardiologists who made more referrals were rewarded with larger bonuses and promotions, while those who gave fewer referrals were punished and their promotions delayed.

146. Dr. Wattar reviewed numerous NOHC patient files that showed that as a result of the referral kickback system there were significant catheterization laboratory procedures and other procedures and tests being performed that were not medically warranted. These procedures resulted in significant false billings being made to Medicare and Medicaid.

B. North Ohio Medical Imaging - NOMI

147. NOMI was an imaging company owned by the NOHC practice. All NOHC physicians were required to refer their patients to NOMI. Both non-partner physicians and partner physicians were given "work unit" credits for each referral made. Work units were valuable credits and essential for maintaining employment, becoming a partner, maintaining health insurance benefits, and for sharing in the NOHC profits at the partnership level. Without work units from referrals, it was virtually impossible to meet work unit goals set by NOHC leadership and to maintain employment or attain or maintain partnership status.

148. Despite the referral and kickback system, NOMI was not sufficiently profitable to pay the debt on the imaging equipment used to provide imaging services. Elyria Hospital agreed to buy NOMI from NOHC and pay off the NOMI debt. In exchange for the purchase and relief

from the debt, the NOHC physicians agreed that they would continue to refer their patients to the NOMI imaging facility, a kickback prohibited by law.

C. Elyria Hospital-NOHC Joint Venture Catheterization Lab at Elyria Hospital

149. Defendant EMH Regional Center's Elyria Hospital allowed the NOHC-Elyria Hospital joint venture catheterization lab to operate on the Hospital's premises.

150. There is no legitimate reason for Elyria Hospital/EMH Regional Center to allow NOHC to jointly operate a catheterization laboratory with NOHC except that this arrangement allowed the hospital to benefit from increased referrals from NOHC to the joint venture. The purpose of this joint venture arrangement was to provide a kickback to the NOHC physicians for the referrals they provided to the cath labs.

D. Competition Impeded by EMH Regional Medical Center and Elyria Hospital

151. Defendant EMH Regional Medical Center, through its Elyria Hospital, provided kickbacks to NOHC physicians by preventing other qualified physicians from having hospital privileges at the hospital.

152. Despite applications and multiple follow-up efforts, physicians from outside the NOHC physician group found that their applications for privileges at Elyria Hospital were mysteriously not acted upon. Not until after the FBI began investigations in 2007 or later did Defendant EMH Regional Medical Center act upon these non-NOHC physician applications.

153. Dr. Nadim Al-Mubarak, a cardiac interventionalist and direct competitor to Dr. O'Shaughnessy, applied for privileges at the Elyria Hospital without success. Dr. Mubarak is a highly qualified, respected interventionalist, with an office in Westlake, Ohio. He had privileges

at four other Cleveland-area hospitals. Dr. Al-Mubarak has authored a number of scientific articles on cardiac interventions, including co-authoring a medical textbook on stenting interventions published by Lippincott in 2004, entitled *Carotid Artery Stenting: Current Practice and Techniques* (List price $149.00). He called several times to inquire about the status of his request for privileges. The Hospital gave no reason for not acting on it.

154. Physicians from another cardiology group in Westlake also tried to be credentialed to treat patients at the Elyria Hospital, but were stymied in their efforts.

E. North Ohio Research (NOR)

155. NOHC had a clinical research arm, called North Ohio Research or NOR, that conducted clinical trials for pharmaceutical companies and device manufacturers. Profits from this entity flowed back to the partners. Research money was distributed to the NOHC partners and checks were issued every 3 months. NOHC doctors who referred patients to the clinical trials received the all-important "work units" for each patient referred and for each patient accepted as a study participant. Referrals to NOR were part of NOHC's "business initiative sharing."

156. NOR was coordinating a study involving Drug-eluting Stents (DES) that were being tested against other stents. NOHC encouraged its doctors and staff to recruit patients. The highest place of recruitment was in Elyria. Many patients entered the trial. Nurses also recruited patients, but most of the study occurred in the Elyria Hospital.

157. The clinical research conducted by NOR was tainted by the "recycling" practices. For example, patients who had unnecessary stents became study participants, when only patients whose medical condition merited a stent should have been participants. Likewise, some patients

who participated in studies involving stents were not appropriate candidates for stents because they failed to meet accepted medical standards for a stent and, thus, were improperly selected to become part of the clinical study.

158. Dr. Sheldon, one of the NOHC interventionalists, was involved in Medtronics clinical trials involving stents. Dr. Wattar reviewed the medical records of a patient in this study and determined that there was no medical indication in the file for a stent. The patient, therefore, was improperly included in the study.

159. Dr. O'Shaughnessy also served as the principal investigator in clinical studies. He did not fulfill the oversight responsibilities, due to his busy schedule, and frequently inappropriate patients were included in his clinical studies.

VII. WORK UNITS WERE USED BY NORTH OHIO HEART CENTER TO ENCOURAGE DOCTORS TO PERFORM UNNECESSARY PROCEDURES AND INCREASE REFERRALS TO RELATED BUSINESS ENTITIES

160. NOHC and its leadership, including Defendants Dr. Schaeffer and Zrimec, strategically employed the "work units" incentive system, combined with vigorous non-compete language in their employment agreements, to instill conformity with their practices. NOHC utilized the work units system to force physicians into participating in the various money-making fraud schemes.

161. Defendant NOHC's work units were combined with threats of costly litigation to enforce non-compete agreement clauses in physicians' employment agreements if a physician objected to the system or contemplated leaving the practice. Other threats made to compel

compliance included reducing compensation or benefits and witholding or postponing partnership decisions to enforce the money-making fraud systems that they had engineered.

162. Dr. Wattar was not participating in the recycling business. He did not refer patients for needless tests or services. In the words of Dr. Schaeffer, he probably did not have sufficient "work ethic" to meet the needs of the NOHC practice. Dr. Schaeffer told him that in order for Dr. Wattar to "sit with those guys at this table," meaning to become a full partner, Dr. Wattar would have to have numbers that looked like their numbers. By this, Dr. Schaeffer meant that Dr. Wattar had to have average work units of 140,000 annually.

A. Monthly Tabulations of Doctors' "Work Units"

163. Defendant Dr. Schaeffer and the NOHC used monthly data about the number of patients being sent by each doctor for other procedures and tests to increase billings and profits. The practice employed a system of work units to measure physicians' contributions to the practice and eligibility for the lucrative partnership shares. Accountability, appropriateness, and quality of services were not measured and were not considered a factor in success or failure at the NOHC. There was, in fact, virtually no peer review system whatsoever and no concerted efforts to improve quality of patient care. Moreover, there was no organized or systemic effort to decrease unnecessary procedures, such as NOHC's abnormally high angioplasty rate.

164. Written reports were circulated at the regular NOHC partnership meetings and oral comments were made about each of the doctors and their work unit "numbers." Dr. Schaeffer and the NOHC pressured doctors to increase referrals to cath labs and other labs. These

written reports reflected the work unit that were credits for the number of referrals to the other businesses.

B. NOHC Leadership Expected at Least 140,000 "Work Units"

165. Defendant Dr. Schaeffer made clear to Dr. Wattar that 140,000 work units was the level at which each doctor was to perform. Dr. Schaeffer continually told Dr. Wattar that he needed to increase his "numbers," meaning work units. To fulfill the 140,000 work unit expectation would have required 12 hours daily of non-stop work seeing patients, or 12 cardiac catheterizations daily. With Dr. Wattar scheduled to see patients 8 am to 5 pm daily and with other office staff leaving at the normal end of the work day, the only way to get to this work unit goal was to generate large numbers of medically inappropriate internal self-referrals to NOHC-related entities and take actions that would lead to needless cath lab and angioplasty procedures.

166. Defendant Dr. Schaeffer said that the physician "work ethic" would allow or not allow a physician to reach the 140,000 work unit level. He said that if you had "work ethic," you would produce the average of 140,000 units annually. What Dr. Schaeffer meant by this was not necessarily that a doctor had to work 80 hours weekly and not take any of the 8 weeks of paid vacation that partners enjoyed. What he meant was that physicians had to do it all: clinical assessments, order all tests, send patients in annually for stress tests, refer patients in large numbers to the other businesses (imaging, research, cath lab), etc. Indeed, to try to meet the 140,000 of work units merely by working hard seeing patients and treating them would have been virtually impossible to a maintain for a physician with family responsibilities and any life outside the practice.

167. The NOHC "work units" calculations and requirements were secret. They were not revealed to Dr. Wattar prior to joining NOHC, nor were they written out in his highly-detailed and thick contractual agreements. His employment agreement simply said that partnership decisions would be based upon discretion.

168. After he joined the practice, every six months Dr. Schaeffer met with Dr. Wattar and told him where he was (how many work units he had earned). That is when he made it clear that the expectation was that Dr. Wattar should produce an average of at least 140,000 work units annually if he was to become a partner.

C. NOHC's Pressures on Doctors to Refer and Recycle Patients

169. NOHC's leadership and cardiology group leader put the cardiologist staff under continual pressure to perform stents and order unneeded procedures. The angioplasty "cash cow" and the "chickens come home to roost" phrases were employed to encourage more and higher billings. Little or no discussion was had at partner meetings or in one-on-one evaluations of physicians by Dr. Schaeffer about quality of patient care or improvements in medical procedures. Instead, the meetings focused on such matters as how the cardiologists were progressing in terms of "work units," which were designed to trace and take into account for compensation purposes the number of stress nuclear tests, stents, and other procedures a cardiologist was ordering or performing.

170. NOHC partnership meetings had little to do with quality patient care and only involved how to maintain the physician's high levels of income. NOHC partners earned substantially more than other physicians who were not NOHC part-owners, termed "partners."

Base pay for physicians was $280,000. Due to the "work units" calculations used to determine productivity bonuses, most NOHC partners earned in excess of $600,000 annually. Several NOHC physicians were paid more than $1,000,000 annually. Total NOHC physician fee revenue fell, however, by about $3 million, from August 2006 until early 2008, after a number of interventionalists left the practice, either permanently or temporarily.

171. NOHC compensation plans were used to threaten partners and coerce them into making the unnecessary referrals and reports that the profit margins demanded. NOHC claimed that they could force physicians to pay for their family health insurance benefits if they did not fulfill minimum work units numbers. NOHC bonuses were paid based upon the number of procedures undertaken, ordered, or generated, such as angiograms, ultrasounds, echocardiograms, etc.

172. Dr. Wattar was told by an NOHC executive board member that one of the reasons Dr. Wattar was not offered a partnership in 2006, when he expected the invitation, was that Dr. Wattar was not sending enough patients to the other NOHC-related businesses. Dr. Wattar only referred patients for more services if it was medically indicated.

173. Defendant Dr. Schaeffer and NOHC did not offer partnership to doctors until they had decided that the physician was ready to "join the club." These decisions were not made based upon medical competency or credentials. Instead, before inviting a doctor to join the partnership, Dr. Schaeffer first made a determination that the physician would be cooperative, not complain about Dr. O'Shaughnessy's stenting rates, refer patients at high rates to diagnostic

services owned by the practice, and generally work under the guidance of Dr. Schaeffer's "work ethic" to make the practice more profitable.

VIII. REPORTING THE FRAUD AND RETALIATION

174. In early 2008, Dr. Wattar was asked to read stress nuclear tests and issue reports necessary for billings to insurance and Medicare in North Ohio Heart's Elryia office At this time, he became aware of and learned about the practice that he came to call the NOHC system of "recycling" patients annually.

175. Dr. Watar reported to Dr. Schaeffer that Dr. Qarab Syed, a fairly new partner, was doing repeat, unnecessary procedures, including these three examples that occurred in late 2006 and into 2007:

a.	Patient # 270543	Stress nuclear test instead of far more appropriate and inexpensive treadmill;
b.	Patient # 293324	Stress nuclear test for a 20-year old healthy woman who fainted;
c.	Patient #275660	Female in her mid-40's who had 3 catheterizations just 4 months apart, all results normal.

The first patient had recently received a stent and was to undergo cardiac rehabilitation and, thus, was not an appropriate candidate for nuclear stress testing. The second patient likely had no cardiac condition whatsoever as she had no other risk factors or symptoms. The third patient had no symptoms of chest pain and had undergone numerous cardiac catheterizations, even though blockages do not develop in 4 months, but over a number of years.

176. Dr. Schaeffer was not interested in Dr. Wattar's review of the Dr. Syed medical records regarding examples of over-testing and inappropriate procedures and would not look at

the records.

177. Dr. Wattar brought his concerns regarding the propriety of excessive nuclear stress testing to the attention of Defendant Gary Zrimec, CEO and head of compliance for North Ohio Heart Center, in mid-2008. Dr. Wattar said he would not continue reading the stress nuclear tests if the pattern of routine testing continued because he did not want to link his name and reputation to such activities.

178. Defendant Zrimec told Dr. Wattar that Medicare allowed annual nuclear stress testing and will pay for the costs associated with such testing and that the group was not going to amend its method of operation regarding the nuclear stress tests. Mr. Zrimec never responded further to Relator and he stopped reading the tests.

179. Dr. Wattar came to North Ohio Heart Center, Inc. in 2004 based in large part on the expectation that he would become a partner in this well-established cardiology group. Dr. Wattar performed well as an employee of North Ohio Heart Center and always received excellent feedback on his clinical skills, knowledge and judgment.

180. As Dr. Wattar became incrementally aware of the breadth of the practice's scheme to perform unnecessary procedures and testing on patients, however, his work environment became increasingly intolerable. Dr. Wattar felt continuously pressured to meet productivity standards by referring patients for procedures and testing that was not medically indicated.

181. Dr. Wattar complained verbally and in writing about how specific patients were treated. In January 2009, he sent an email to Dr. Schaeffer regarding his 83-year old patient who

was subject to unnecessary procedures that presented a risk to her health and were ultimately harmful to her.

182. Dr. Wattar's patient came to him complaining of dizziness, but no chest pain or other cardiac symptoms, and he suggested she see a vascular surgeon outside the NOHC practice in light of the fact that she had previously had carotoid surgery, a type of vascular surgery. The vascular surgeon ordered an angiogram on her carotoid arteries, which was to be performed by Dr. O'Shaughnessy. When he went to perform the angiogram, Dr. O'Shaughnessy found the carotoids clear, so then he scheduled her for multiple angioplasty interventions on her arm and heart. Both of these conditions of proximal stenosis had been well-documented in her medical records for years, including by cardiologists at the Cleveland Clinic who had performed open heart surgery (CABG) on her in 2002. The consensus of all of her treating physicians had been that she was not an appropriate patient for intervention as to this stenosiscondi because the risks of intervention outweighed any potential benefits.

183. Dr. O'Shaughnessy falsified the patient's records to show chest pain, although she did not have any. As a result of Dr. O'Shaughnessy's interventions, as to which he did not consult with Dr. Wattar at any time, the patient experienced complications that have diminished her quality of live, including bleeding from the groin. She is now taking Plavix and Coumadin, which she was not taking previously.

184. North Ohio Heart Center responded to Dr. Wattar's concerns by whitewashing the event with a rigged "peer review" panel that included Dr. O'Shaughnessy, the interventionalist who had performed the unneeded, unauthorized, and harmful procedures on the patient, but did

not include Dr. Wattar in any way. The peer review panel exonerated Dr. O'Shaughnessy, even though the procedures were not reasonable and conducting them was unnecessary and harmful to the patient.

185. After Dr. Wattar made his January 2009 complaint in writing about the events with his 83 year-old patient, Dr. Schaeffer and NOHC began retaliating against Dr. Wattar, cutting his base pay, denying him bonuses, and refusing to pay other benefits.

186. Dr. Wattar determined that the work environment, including the process of ordering and performing unnecessary tests and procedures had become so unbearable that no reasonable person could endure it and in late March 2009, Dr. Wattar resigned. NOHC made clear that it would enforce his non-compete provisions in his employment contract with the practice and asked him to leave prior to the 90-day notice period he was required to provide NOHC under the contract. Dr. Wattar then left his home in northern Ohio and moved 200 miles away, earning substantially less than what his income would have been had he joined the NOHC partnership.

187. Prior to filing his qui tam action, in July 2009, Dr. Wattar met voluntarily with the FBI and U.S. Department of Justice to provide information helpful to them. Dr. Wattar cooperated with the investigation and provided his records to the FBI.

188. Defendants NOHC and Dr. Schaeffer preferred that physicians peform multiple stents, rather than have the patients undergo surgery, which entailed referral to the Cleveland Clinic physicians who performed open heart surgery at Elyria Hospital. Generally, if you need surgery, then you have at least 3 blockages. Generally acceptable medical practice for over a

decade is to perform open heart surgery rather than insert stents if there are 3 or more blockages of more than 50% blockage.

189. Dr. Felipe Navarro trained at the Cleveland Clinic and is very well-credentialed. NOHC caused him to be removed from providing services at the cath lab at Elyria Hospital in about 2006 because he was outspoken about putting the unnecessary stents he was observing. He only was with the practice in Elyria for 10 months. He took pictures and showed the doctors that stents were put on arteries only 20% narrowed.

190. Dr. Hamoud told Dr. Wattar about Dr. Stephen Moore and Dr. O'Shaughnessy that he observed during his work with NOHC at Elyria Hospital.

IX. DEFENDANTS IMPROPERLY BILLED MEDICARE AND MEDICAID, INCLUDING FOR UNNECESSARY SURGERIES AND PROCEDURES

191. For a service to be reimbursable by Medicare, it must be "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part." Defendants, however, performed unnecessary tests and procedures and submitted those claims to Medicare as if they were reimbursable.

192. By submitting a claim to Medicare and accepting payment for that claim, a health care provider is certifying that the services are being provided economically and only to the extent medically necessary, that the services are of a quality which meets professionally recognized standards of health care, and that all services provided are supported by evidence of such medical necessity and quality.

193. Defendants routinely falsely certified to Medicare, and therefore the Government, that cataract surgeries were medically necessary and that exams met the professionally recognized standard of care.

194. Defendants wrongly caused Relator Dr. Wattar's termination for his refusal to take part in their scheme to conduct medical tests and procedures that were unnecessary and not medically necessary or reasonable and resulted in false claims and false billings to Medicare, Medicaid, and other federal, government, and private payors and which, in some instances, resulted in harm to patients.

COUNT I
False Claims Act - Presentation of False Claims
31 U.S.C. § 3729(a)(1), 31 U.S.C. § 3729(a)(1)(A) as amended in 2009

195. The allegations of the preceding paragraphs and those that follow in subsequent Counts are re-alleged as if fully set forth below.

196. Through the acts described above, Defendants and their agents and employees knowingly presented and caused to be presented to an officer or employee of the United States Government a false and/or fraudulent claim for payment or approval in violation of 31 U.S.C. § 3729(a)(1), and, as amended 31 U.S.C. § 3729(a)(1)(A).

COUNT II
False Claims Act - Making or Using False Record or Statement to Cause Claim to be Paid
31 U.S.C. § 3729(a)(2), 31 U.S.C. § 3729(a)(1)(B) as amended in 2009

197. The allegations of the preceding paragraphs and those that follow in subsequent Counts are re-alleged as if fully set forth below.

198. Through the acts described above and otherwise, Defendants and their agents and employees knowingly made, used, and/or caused to be made or used false records and statements in violation of 31 U.S.C. §§ 3729(a)(2), and, as amended 31 U.S.C. § 3729(a)(1)(B) in order to get such false and fraudulent claims paid and approved by the United States Government.

COUNT III
False Claims Act - Conspiracy
31 U.S.C. § 3729(a)(3), 31 U.S.C. § 3729(a)(1)(C) as amended in 2009

199. The allegations of the preceding paragraphs and those that follow in subsequent Counts are re-alleged as if fully set forth below.

200. Through the acts described above and otherwise, Defendants and their agents and employees entered into a conspiracy or conspiracies to defraud the United States by getting false and fraudulent claims allowed or paid in violation of 31 U.S.C. § 3729(a)(3), and as amended 31 U.S.C. § 3729(a)(1)(C). Defendants also conspired to omit disclosing or to actively conceal facts which, if known, would have reduced government obligations to pay them or resulted in repayments to Defendants from government programs.

201. Defendants and their agents and employees took substantial steps in furtherance of those conspiracies, including but not limited to, by preparing false records, by submitting claims for reimbursement to the Government for payment or approval, and by directing its agents and personnel not to disclose and to conceal their fraudulent practices.

202. The United States, unaware of Defendants' conspiracy or the falsity of the records, statements and claims made by Defendants and their agents and employees, and as a result

thereof, has paid and continues to pay millions of dollars that it would not otherwise have paid. Furthermore, because of the false records, statements, claims, and omissions by Defendants and their agents and employees, the United States has not recovered federal funds from the Defendants that otherwise would have been recovered.

COUNT IV
False Claims Act - Making or Using False Record or Statement to Conceal, Avoid or Decrease Obligation to Repay Money
31 U.S.C. § 3729(a)(7), 31 U.S.C. § 3729(a)(1)(G) as amended in 2009

203. The allegations of the preceding paragraphs and those that follow in subsequent Counts are re-alleged as if fully set forth below.

204. Through the acts described above, in violation of 31 U.S.C. § 3729(a)(7) and as amended, 31 U.S.C. § 3729(a)(1)(G), Defendants and their agents and employees knowingly made, used, and caused to be made or used false records and statements to conceal, avoid, and/or decrease Defendants' obligation to repay money to the United States Government that Defendants improperly and/or fraudulently received, including through false statements contained in Defendant Elyria Regional Hospital's cost reports submitted to the United States. Defendants failed to disclose material facts that would have resulted in substantial repayments to the United States.

COUNT V
False Claims Act Retaliation Violation
31 U.S.C. § 3730(h)

205. The allegations of the preceding paragraphs and those that follow in subsequent Counts are re-alleged as if fully set forth below.

206. Defendant NOHC has a duty under the False Claims Act, 31 U.S.C. § 3730(h), to refrain from taking retaliatory actions against employees and others who take lawful actions in furtherance of a False Claims Act action, including investigation for, testimony for, or assistance in an action filed under this section.

207. Relator took lawful actions in furtherance of a False Claims Act action, including investigation for and assistance in an action filed under this section and, as such, engaged in protected activity under the False Claims Act and other laws.

208. While employed by Defendant NOHC and after his employment was illegally terminated, Relator questioned, investigated, and reported internally and subsequently to appropriate Government officials, Defendant's improper practices and billing in furtherance of a False Claims Act action.

209. Because Defendant NOHC knew, by 2008, that the United States Government had initiated an investigation of aspects of NOHC's medical and billing practices, and because NOHC had engaged counsel, including but not limited to Richard C. Panza, with regard to that investigation, Defendant NOHC knew or should have known that Relator's activities investigating and opposing their unlawful conduct, including his investigation of and assistance in an action filed under this section, were in connection with a False Claims Act action.

210. Defendant NOHC retaliated against Relator for his lawful actions taken in furtherance of a False Claims Act action, including but not limited to his investigation and assistance in an action alleging Defendants' violations of the False Claims Act and Relator's efforts to prevent further False Claims Act violations by Defendants.

211. Due to the non-compete provisions in his NOHC employment agreement, which is similar to that of most or all NOHC physicians, Dr. Wattar was told by NOHC that it would take legal action if he entered into a competing cardiology practice in the area around Cleveland and the other locations of the practice. Thus, he searched for employment at a greater distance and by early April 2009 he was offered and had accepted a position at a Butler, County, Ohio hospital, Ft. Hamilton Hospital, in Hamilton, Ohio, about 25 miles north of Cincinnati.

212. Dr. Wattar gave the contractually-required 90 days notice to NOHC that he was leaving; however, NOHC abruptly terminated him prior to the expiration of his 90 day notice period when it told him to leave on April 30, 2009, resulting in a constructive discharge on that date.

213. The actions taken by Defendant NOHC in violation of 31 U.S.C. § 3730(h), damaged and will continue to damage Relator in an amount to be determined at trial.

214. Defendant's misconduct and illegal treatment of Relator has had a chilling effect, stifling reports of Defendant's False Claims Act violations. Defendant NOHC's retaliation against Relator effectively warned other NOHC physicians, employees and the related NOHC entities that they should not engage in honest and open reporting of Defendant's misconduct.

215. Pursuant to 31 U.S.C. § 3730(h), Relator is entitled to litigation costs, expenses, and reasonable attorneys' fees incurred in the vindication of his reputation and the pursuit of his retaliation claims.

COUNT VI
Ohio Public Policy Tort

216. The allegations of the preceding paragraphs and those that follow in subsequent Counts are re-alleged as if fully set forth below.

217. It is the public policy of the state of Ohio, as articulated by various statutory provisions and the common law, that theft offenses, including theft by deception and fraud, shall not be tolerated.

218. It is further the public policy of Ohio that witnesses to criminal activity shall not intimidated or coerced, as evident by R.C. 2905.11, R.C. 2905.12, R.C. 2921.02 and R.C. 2921.03, among other statutes and regulations, such that the policy against theft through fraud may be furthered by the law enforcement and judicial systems. It is further the public policy of Ohio that no one shall obstruct justice as evidenced by R.C. 2921.32 (A)(4) and (A)(5) nor obstruct official business as evidenced by R.C. 2923.31. It is further the public policy of Ohio, as found in the constitutional, statutory and regulatory provisions, that persons shall be free to express themselves on matters of public interest.

219. Adverse employment actions taken against those opposing such activities jeopardize the public policies identified above.

220. Relator reasonably believed that Defendants were defrauding Medicare and, therefore, the Government, when they submitted claims for unnecessary procedures and tests, and overbilled by unbundling procedures into separate billings when unbundling was neither necessary nor reasonable.

221. Relator repeatedly protested to the Defendants that Defendants' unlawful practices would lead and had, in fact, already led to patient harm.

222. Defendants' response to Relator's objections was to constructively discharge Relator on April 30, 2009.

223. As a direct and proximate result of Defendants' unlawful, retaliatory conduct, Relator has suffered and will continue to suffer non-economic and economic injuries, including but not limited to pain and suffering and the loss of salary, benefits and earning capacity for which Defendants are liable.

COUNT VII
Breach of Contract

224. The allegations of the preceding paragraphs and those that follow in subsequent counts are realleged as if fully set forth below.

225. Defendant NOHC and Dr. Wattar entered into a contractual employment agreement ("Employment Agreement") regarding his employment with NOHC (copy attached).

226. Defendant breached the Employment Agreement when it required Dr. Wattar to engage in unlawful conduct in order to maintain good standing in his employment. On or about April 30, 2009, Defendant NOHC further breached the Employment Agreement without cause or justification when it caused Dr. Wattar's termination of employment.

227. As a direct and proximate result of Defendant's conduct, Relator has suffered and will continue to suffer economic injuries for which Defendant NOHC is liable, including but not limited to loss of salary, benefits and earning capacity, attorney fees, costs and other relief the court may deem proper.

COUNT VIII
Fraudulent Inducement

228. The allegations of the preceding paragraphs and those that follow in subsequent counts are realleged as if fully set forth below.

229. Defendants, at the time of Relator's hire and at various times thereafter, represented to Relator that they wanted him to join the partnership without disclosing to Dr. Wattar that they had engaged and were engaging in practices that violated Medicare, Medicaid, and other legal requirements for providing medical services and billing those services.

230. Defendants NOHC, Schaeffer, and Zrimec made false representations with knowledge of their falsity or with utter disregard and recklessness about their falsity to Relator. Defendants NOHC, Schaeffer, and Zrimec also knowingly concealed and omitted material information from Relator that they had a duty to disclose.

231. Defendants NOHC, Schaeffer, and Zrimec's representations, omissions, or concealments were material to Relator's decision to accept employment and remain employed with NOHC, and were made to Relator with the intent to mislead Relator into relying on such representations.

232. Relator Wattar justifiably relied on Defendants NOHC, Schaeffer, and Zrimec's representations, omissions, or concealments to his detriment and was fraudulently induced to sign the Employment Agreement. Had Relator been aware of Defendants' unlawful practices, he would not have agreed to sign the Employment Agreement.

233. Relator has complied with all of the obligations set forth in the Employment Agreement with NOHC, including a non-compete provision precluding him from practicing his

cardiology specialty in the Cleveland area after his constructive discharge from NOHC on April 30, 2009.

234. As a direct and proximate result of Relator's justifiable reliance on Defendants' representations, omissions, or concealments, Relator has suffered and will continue to suffer economic damages.

COUNT IX
Promissory Estoppel

235. The allegations of the preceding paragraphs and those that follow in subsequent counts are realleged as if fully set forth below.

236. Defendant NOHC made clear and unambiguous promises to Relator that he would be employed in a bona fide medical practice undertaken in accordance with the law, high practice standards, and medical ethics.

237. Defendant NOHC and their agents and employees should have reasonably expected that their promises to Relator would induce Relator to give up other employment options and perform services on NOHC patients based on their promises.

238. Dr. Wattar, did, in fact, accept employment and ceased looking for other employment in reliance upon Defendant's promises.

239. As a direct and proximate result of Relator's detrimental reliance on Defendant NOHC's promises, he has suffered economic damages.

COUNT X
Tortious Interference with Contract and Employment Relationship

240. The allegations of the preceding paragraphs and those that follow in subsequent counts are realleged as if fully set forth below.

241. At all material times hereto, Relator had a contractual and employment relationship with NOHC in his role as a physician and cardiologist.

242. At all material times hereto, Defendants Schaeffer, Zrimec, O'Shaughnessy, and Thome were aware of the existing contractual and employment relationship between Relator and NOHC.

243. As a direct and proximate result of Defendants Schaeffer, Zrimec, O'Shaughnessy, and Thome's purposeful, intentional and unjustified interference with Relator's contractual and employment relationship with NOHC, Relator has suffered and will continue to suffer non-economic and economic injuries, including but not limited to pain and suffering and the loss of salary and benefits for which Defendants are liable.

244. Defendants Schaeffer, Zrimec, O'Shaughnessy, and Thome's conduct, as described above, was willful, wanton, reckless, and/or malicious, rendering them liable for punitive damages and attorneys fees.

COUNT XI
Intentional Infliction of Emotional Distress

245. The allegations of the preceding paragraphs and those that follow in subsequent counts are realleged as if fully set forth below.

246. Defendants engaged in a sustained mode of conduct while in the course and scope of their executive management positions at North Ohio Heart Center of harassing Relator that was so outrageous in character and extreme in degree as to go beyond all possible bounds of decency, so as to cause Relator severe emotional distress.

247. As a direct and proximate result of Defendants' conduct, Relator has suffered emotional distress of such nature that no reasonable person could be expected to endure.

248. Defendants' outrageous conduct was malicious, willful, wanton, and/or in conscious disregard of Relator's rights under the law, rendering them liable for punitive damages and attorneys fees.

PRAYER FOR RELIEF

WHEREFORE, Relator Abdul Wattar requests that judgment be entered against Defendants, ordering that:

A. Defendants cease and desist from violating the False Claims Act, 31 U.S.C. § 3729, *et seq.*;

B. Defendants pay not less than $5,500 and up to $11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of the Defendants' actions;

C. Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d);

D. Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d);

E. Relator be provided with injunctive or equitable relief, as may be appropriate, to prevent further harm to himself and to prevent the harm to others and the public caused by Defendants' retaliation against him as a whistleblower;

F. Relator be awarded all damages, litigation costs, expert fees, and reasonable attorneys' fees incurred as provided pursuant to 31 U.S.C. § 3730(h) and other applicable law;

G. Relator be awarded all damages resulting from Defendants' breach of contract and other personal claims;

H. Relator be awarded damages in excess of $25,000 plus including attorneys' fees, interest, costs for pain and suffering, anxiety, emotional distress, and any other relief the court may deem appropriate;

I. Relator be awarded all other damages to which he is entitled, including punitive damages;

J. Defendants be enjoined from concealing, removing, encumbering or disposing of assets that may be required to pay the civil monetary penalties imposed by the Court;

K. Defendants disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

L. The United States and Relator recover such other relief as the Court deems just and proper.

Respectfully Submitted,

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REQUEST FOR TRIAL BY JURY

Relator hereby demands a trial by jury.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing First Amended Complaint was served this 14th day of January, 2011, upon the following:

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